

REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR §589.2000

(Version 3.1, 9/14/01; FDA/CVM, HFV-230)

FEI # (required):

Firm (Legal) Name: _____ Date Inspection Ended: _____
Firm (Physical) Address: _____ Lead Investigator: _____
Firm City: _____ Lead Affiliation (*circle one*) **STATE** **FEDERAL**
Firm State: _____ ZIP Code: _____ Phone #: _____ FDA District Office (*required*): _____

Name and title of person interviewed: _____

Inspection Conclusion: (*Check only one*) ☐ RTC ☐ NAI ☐ CI ☐ Inactive ☐ Out of Business
[Read Instructions] [FORM IS COMPLETED!] [Skip ALL Sections!]

Section 1 – Complete for ALL firms

1. Type of firm inspected? (*Check all that apply*)

- | | | |
|---|--|---|
| <input type="checkbox"/> Renderer | <input type="checkbox"/> FDA Licensed Feed Mill | <input type="checkbox"/> On-farm Feed Mixer |
| <input type="checkbox"/> Protein Blender | <input type="checkbox"/> Non-FDA Licensed Feed Mill | <input type="checkbox"/> Feeder of Ruminants |
| <input type="checkbox"/> Transporter (Hauler) | <input type="checkbox"/> Pet Food Manufacturer | <input type="checkbox"/> Feeder of Ruminants and Other Species |
| <input type="checkbox"/> Distributor/Retailer | <input type="checkbox"/> Animal Feed/Pet Food Salvager | <input type="checkbox"/> Other: _____ |

2. Does the firm receive feed ingredients or feeds that contain or may contain prohibited material (with the exception of pet food sold at retail and laboratory animal feed)? ☐ YES ☐ NO

a) If “NO,” check all of the following that describe any safeguards the firm has in place to assure they do not receive prohibited material.

- ☐ Assurance from supplier that they no longer manufacture any products containing prohibited materials
- ☐ Labeling review of incoming materials
- ☐ Use only vegetable source proteins
- ☐ Uses pure animal proteins only from exempted sources (examples: such as porcine, equine, poultry, fish, gelatin)
- ☐ Other, (please describe) _____

[If ONLY Feeder of Ruminants or Feeder of Ruminants and Other Species, SKIP to Section 3;
Otherwise, FORM IS COMPLETED - Skip ALL Remaining Sections!]

b) If “YES,” then continue on ...

3. Does the firm receive prohibited material for further distribution **ONLY**? ☐ YES ☐ NO
4. Does the firm manufacture or process products containing prohibited materials? ☐ YES ☐ NO
- a) If “YES,” is imported (not originating in the United States) prohibited material used? ☐ YES ☐ NO ☐ Unknown
- Please list the country/ies of origin for the prohibited material, _____

5. Are the received feed ingredients or feeds containing prohibited materials (referred to in #2 above) labeled with the caution statement, “**Do not feed to cattle or other ruminants**” (with the exception of pet food sold at retail and laboratory animal feed)? ☐ YES ☐ NO

(continued)

- 14.** Are you attaching any further descriptions or any exhibits or records and/or labeling? ☐ YES ☐ NO

INSTRUCTIONS – For the Lead Investigator

BSE Coordinator. The FDA BSE District Coordinator is responsible for communicating and receiving information related to the BSE Checklist. Questions, comments and concerns should be directed to this individual. All completed BSE Checklists should be mailed **only** to the BSE Coordinator and not directly to CVM.

BSE Checklist Version. Please make sure that you are using the most current BSE Checklist. The version date is located at the bottom right-hand corner of the form. Check with your BSE Coordinator to make sure that you are using the most recent version. The use of any other version will not be compatible with the BSE Checklist Database and may invalidate the information that you collect.

BSE Checklist Alterations. Some agencies may need to alter the BSE Checklist to better fit their own operations. While CVM does not necessarily object to such alterations, all changes must be added to the end of the form. No additions, deletions or revisions should be made to the main body of the CVM-version of the BSE Checklist.

Legibility. Illegible writing results in inaccurate data, which compromises the BSE Checklist Program. If at all possible, type in your responses. If handwritten, please print letters rather than using longhand.

Completing Sections. Sections should be fully completed for each of the firm types indicated in the header of each Section. Sections that are inappropriately skipped (based on the firm type) will cause the BSE Checklist to be considered incomplete and unacceptable for submission to FDA/CVM.

Completing Questions. The BSE Checklist instructions and flow of questions must be followed. Blank or unanswered required questions will cause the BSE Checklist to be considered incomplete and unacceptable for submission to FDA/CVM.

Descriptive Fields. For those questions that ask for an explanation or description, please be brief and capture the essential elements with as few words as possible. If you feel that certain answers require a more lengthy description, please consider recording the answer on a separate page, which should be attached to the BSE Checklist and so noted in **Question 14**.

Form Is Completed. The instruction “Form Is Completed” means that the investigator needs NOT fill in anymore of the BSE Checklist. Ignore all remaining sections, including Section 4.

FEI Number. The FEI number is absolutely required. You may need to contact your BSE District Coordinator for this information.

Firm Name. Firm names should be consistent with the FDA FACTS database. “Doing Business As” (DBA) names are unacceptable.

Firm Address. The address should reflect the physical location of the firm’s activities. Post Office Box numbers are unacceptable.

Inspection Conclusion. This code represents the investigator’s reported conclusion and is generally recorded in the FDA FACTS database. You may need to consult with your BSE Coordinator. **RTC** = Referred to Center; **NAI** = No Action Indicated; **CI** = Correction Indicated. Forms should be completed for **Inactive** firms since they might begin production at any time. **Out of Business** firms require no more information gathering.

Firm Type. Please understand the firm type categories provided and use these categories whenever applicable.

Considerations:

- A single firm can be categorized as one or more firm types.
- The BSE Checklist may not fully describe the activities of certain multiple firm type combinations. Please contact your BSE District Coordinator if additional guidance is needed.
- Feed mills should be described on the basis of FDA licensure and NOT on whether the firm produces medicated feeds.
- Ruminant feeders (e.g. dairy farms) might also be On-farm Mixers.
- On-farm Mixers might not be ruminant feeders (e.g. swine farms).
- On-farm Mixers, regardless of the species being fed, are subject to the requirements of the BSE regulation.
- On-farm Mixing applies to mixing that is not performed for the purpose of commercial distribution. Generally the use of on-farm mixed feeds is limited to the same farm premises and so requires minimal controls. However, on-farm mixed feeds that are utilized off-premises and/or outside the direct supervision of the farm manager (e.g., a farm where mixed feeds are delivered for feeding at physically different farm locations, perhaps under a contract arrangement) should be produced under all control measures required by the BSE regulation.
- The “Other” category should be used only for firm operations that are not described by the other categories. Improper use of the “Other” category may cause inaccurate and/or inadequate information to be collected in the remaining Sections.

Feed Ingredients and Feeds. This category refers to substances that are either utilized the manufacture of animal feeds or that are intended to be feed to animals. Substances intended solely for other purposes (e.g. fertilizers) are not included in this category.

Question 11a. Please keep in mind that potential sources of prohibited materials also include pet foods and salvaged pet foods.

INSTRUCTIONS – For the BSE District Coordinator

The BSE District Coordinator has a key role and overall responsibility for ensuring that BSE Checklists are completed fully and accurately, which is vital to the success of BSE compliance efforts. The BSE District Coordinator should pay particular attention to ensuring the following:

- Familiarity with the Instructions for the Lead Investigator.
- The most recent version of the BSE Checklist and accompanying instructions are distributed and utilized.
- The BSE Checklist has not been unacceptably altered.
- All required sections are completed. All questions within a required section are completed.
- Handwritten forms are legible.
- The FEI number is provided
- The FDA District Office identity is provided.
- The Inspection Conclusion is provided.
- Response inconsistencies are resolved.

All completed BSE Checklists should be sent to the BSE District Coordinator and not directly to CVM. The BSE District Coordinator, after checking the forms for completeness and accuracy, will in turn send (not fax) copies of the forms via FedEx within ten (10) days to CVM at the following address:

BSE Compliance Program
FDA/CVM (HFV-230)
Division of Compliance
7500 Standish Place
Rockville, MD 20855-2773

Any questions, concerns or comments regarding the BSE Checklist or the BSE Compliance Program should be directed to the following BSE Compliance Program Contacts:

CVM: Neal Bataller
Nbatalle@cvm.fda.gov
301-827-3353

ORA: Jim Dunnie
Jdunnie@ora.fda.gov
301-827-5652